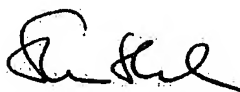


Verification

I do hereby declare that the translated document attached and certify that, to the best of my knowledge and belief, the attached document contains the statement is a true and accurate translation corresponding to German Patent Application No. DE10224493.6.

Munich, September 10, 2007



Robert Schneckenhühl, Patent Attorney

METHOD FOR CONTROLLING A DEVICE FOR TREATING THE HUMAN EYE

The present invention relates to a method for controlling a device for the ablation of parts of the human eye, by means of laser irradiation, the control being exercised by an
5 electronic data-processing system and a device for treating the human eye by means of laser irradiation.

In ophthalmic surgery a series of methods are known which make possible, with or without additional invasive procedures, an abrasion of parts of the cornea surface to correct sight
10 defects. In particular the PRK and LASIK methods may be named here.

A problem when carrying out such treatment procedures is the fact that slight changes in the treatment parameters can have a marked effect on the success of the treatment. Reliance is usually placed here on the experience of the doctor in attendance, the
15 assumption being that he is aware of the significance of the effect of all the parameters.

The object of the present invention is therefore to provide a method for controlling a device for treating the human eye which provides a simple overview of the effect of all the
20 parameters.

This problem is solved by a method according to claim 1. It is provided according to the invention that once the optical and geometric eye data have been established a graphic simulation of the ablation is carried out in the form of a graphic visualization. During the graphic visualization, in particular the pachymetry of the cornea before and after the
25 treatment procedure is represented graphically. The optical and geometric eye data are in particular thickness (pachymetry) and also the curvature of the cornea (topography). These data can be summarized for each eye in a pachymetry map and a topography map. In this way, the doctor in attendance can graphically anticipate the result of the treatment procedure and in particular recognize problem areas. In addition, problems that can be
30 expected, such as too small a residual thickness of the cornea in part areas, can be established by the computer software used and displayed as a warning. In particular for the correction of several sight defects, an optimum parameter configuration can be discovered

with the help of the method according to the invention, for example by varying one or more parameters. This makes it possible to optimize the ablation for example to a minimum abrasion of the cornea. All the parameters can be entered or automatically recorded by means of the computer software which contains all the reciprocal relationships and which can thus calculate a correction which takes all the relevant factors into account. However the weighting and selection of the parameters is not unequivocal, but determined by various patient-specific objectives; e.g. best sight during the day, best sight at dusk, smallest corneal abrasion or similar. The computer software includes an operating interface with the help of which, using the weighting presented previously, the doctor can swiftly arrive at an optimum correction. A mode can also be selected which makes possible a manual adjustment of all parameters, e.g. via scroll boxes or similar displayed on the operating interface. The effect of the parameter changes is illustrated directly via a graphic simulation of the correction.

All the treatment parameters that are to be entered manually are preferably entered by means of a central input/output device. This can be for example a computer screen connected to a keyboard or a so-called touch screen.

In a development of the method according to the invention it is provided that the establishment of the operating parameters comprises of the following process steps: establishment of topography data of the eye; establishment of refraction data of the eye; establishment of higher-order aberration data by wave-front measurement; establishment of pachymetry data; calculation of height data of the deviations relative to a reference surface; calculation of a height data difference relative to the reference surface; calculation of an adapted height data difference relative to the reference surface; calculation of ablation coordinates for the laser.

In the topography data, K values and/or a curvature map and/or a topography map and/or a power map are incurred. In the refraction data, the spherical and/or cylindrical refraction correspondingly are incurred. The reference surface as regards the topography data is an ellipsoid, the reference surface of the refraction data is correspondingly a spheroid. Additional parameters such as special patient wishes regarding visual acuity distribution or similar are included in the adapted height data difference.

In a development of the method according to the invention it is provided that in a further intermediate step, height data deviations of the cornea surface relative to a reference surface are calculated from the topography and/or refraction data. The height data are
5 stored as a height data map of the deviations and can be visualized graphically.

In a development of the method according to the invention it is provided that in a further intermediate step the tissue to be abraded from the cornea is determined from the height data of the deviations of the cornea surface.

10

In a preferred version the device for treating the human eye includes a laser and/or means for wave-front measurement.

The problem named at the outset is also solved by a device for treating the human eye by
15 means of laser irradiation comprising an apparatus for measuring aberrometry, an apparatus for measuring topography, an apparatus for measuring pachymetry, a laser unit and also an electronic data-processing apparatus which by using a treatment model can link the measurement values and further patient data to ablation values. The device preferably includes a measuring equipment arrangement which allows the measurement of
20 aberrometry, topography and pachymetry by means of a fixing. For this, the device has a combination of the necessary measuring instruments which make possible a measurement of the eye to be treated via a common eyepiece. The treatment model is realized as a software module. By treatment model is meant that the software can calculate, on the basis of the measured or manually entered parameters, the ablation for each individual point of
25 the cornea surface. A weighting of all the measurement values or parameters is carried out by the software. The software thus represents a central recording and evaluation tool. The ablation for each point of the cornea surface produces an ablation map. The device is preferably capable of displaying the ablation for each point graphically summarized as an ablation map.

30

The measuring instruments can also be arranged at least partly separately, their measurement results having to be imported manually into the device, or connected to the

device by means of a data bus such as e.g. a serial cable so that their data can be automatically imported.

Advantageous designs of the invention are explained further in the drawings. There is
5 shown in:

Fig. 1 a flowchart of the method;

Fig. 1 shows a flowchart of the method according to the invention. Initially, the optical
10 data of the eye are recorded in a first step. For this the topography is initially established in the form of K-values; a curvature map, a topography map and a power map of the cornea. Pupil data and centring data such as the line of view are also included.

In a next step more subjective refraction data, namely the spherical and cylindrical
15 refraction of the patient, are established. This can be achieved for example by means of a refractometer.

The higher-order aberrations are objectively established by means of a wave-front
20 measurement. Known devices and methods for wave-front measurement can be used for this.

In a further step, height data of the deviations of the cornea surface relative to a reference
surface are calculated from the thus-established refraction or topography data. They are
established from refraction data, applying the standard algorithms, for example the
25 Munnerlyn formulae. A sphere is used as assumed reference surface.

In a further step the height data are derived from the topography data. The curvature of the
reference surface is established using the refraction data. Here too the data are calculated
using standard algorithms such as Munnerlyn formulae. The K-values are also taken into
30 account here. An ellipsoid is used as assumed reference surface.

In a further step, the refraction data are linked to the data of the wave-front measurement.
The curvature of the reference surfaces is established using the refractive data. The

subjective refractions are calculated applying standard algorithms such as the Munnerlyn formulae and overlaying the thus-established data with high-order (HO) data. A sphere is used as assumed reference surface.

- 5 In a third step the refraction data are linked to the topography data and the data of the wave-front measurement. Here too these values are overlaid with high order data in consideration of the K values applying standard algorithms such as the Munnerlyn formulae. An ellipsoid is used here as assumed reference surface. The difference in the topography data vis-à-vis the data established with the wave front measurement is
10 problematic.

- In a further step the height data difference relative to the reference surface is now calculated. A chart (data map) is calculated with height data relative to the deviations to the reference surface. The height difference relative to the reference surface, and thus the
15 tissue to be abraded is given for each point of the cornea surface.

- When applying the LASIK procedure, the flap thickness, the flap diameter and the direction of the fold (hinge side) of the flap are determined. Furthermore, data relating to pachymetry, the thickness of the cornea, are included in the form of a pachymetry map.
20 The effects of pachymetry on the ablation depth are determined. In addition, further patient data such as the age and the cylinder data of the patient are included. Effects on the correction of the refraction and correction of the cylinder axis are also calculated from these.

- 25 Depending on the method to be carried out, for example PRK or LASIK, process-typical effects on the nomograms and the refraction are established.

- In addition certain optimizations are taken into account, e.g. TSA, Night Vision, ASAP grade. A reference surfaces fit is brought about in each zone with a Z shifting.

30

With the parameters shown above, patient-adapted (customized) height data differences relative to the reference surface are established from the height data difference relative to the reference surface. This results in an adapted data map with height data of the deviation

relative to the reference surface. The ablation algorithms are realized with these data. This produces as a result the output of the residual thickness, the ablation volume and the residual defect.

- 5 In addition to the previously established data the influences of the laser parameters, in particular the energy density distribution, the firing frequency, the spot geometry and also the resolution accuracy of the scanner are taken into account. In addition the data with regard to smoke and thermal problems are incorporated.
- 10 In addition, reflection and projection data are established, in particular the change in energy density distribution and reflection losses. This yields correction data for the ablation target data.

- 15 Finally, ablation coordinates for the laser are issued, in this case coordination data for specific lasers (for example MEL 70).

- The established and calculated data can be issued on a computer screen in the form of a graphic simulation. The simulation displays the cornea to be treated, for example in different colours or similar in top view or in section so that the doctor in attendance can
- 20 assess the whole procedure in advance.

* * * * *